K040946

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SECTION 15: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

15.1 SUBMITTER INFORMATION

a.	Company Name:	FRIADENT GmbH.
b.	Company Address:	Steinzeugstrasse 50 Mannheim D-68229 Germany
c.	Company Phone: Company Facsimile:	(011) 49 06 21 4 86 1549 (011) 49 06 21 4 86 1866
d.	Contact Person:	Heike Dietzler Regulatory Affairs Manager
e.	Date Summary Prepared:	April 7, 2004

15.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	ANKYLOS® Dental Implant System
b.	Classification Name:	Endosseous Dental Implants 21 CFR 872.3640

15.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Dentsply Ceramco	ANKYLOS® Dental Implant System	K012681	08/22/2003

15.4 DEVICE DESCRIPTION

The ANKYLOS dental implant system has been previously cleared for commercial distribution. The purpose of this application is to present additional instructions for use sheets for the product. The system and methodology of implantation has not changed with the new labeling.

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15.5 SUBSTANTIAL EQUIVALENCE

The ANKYLOS® Dental Implant System is substantially equivalent to the current ANKYLOS® Dental Implant Systems in terms of design, materials, coatings, mechanical strength, prosthetic options and indications for use.

15.6 INTENDED USE

The ANKYLOS® dental implant is an endosseous dental implant that is indicated for surgical placement in the upper or lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on 4 interforaminal placed implants, and not indicated for single, unsplinted implants. Patient's must be subject for dental treatment with endosseous implants.

15.7 TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the ANKYLOS® Dental Implant System have not changed with the additional of the new labeling.

15.8 CLASS III CERTIFICATION AND SUMMARY

This notification contains a Class III certification and summary of adverse safety and effectiveness information pursuant to 513(f) of the Federal Food, Drug, and Cosmetic Act.

15.9 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewers Checklist is provided in this submission. Comparison of the ANKYLOS dental implant systems to the predicate device show that the device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 0 1 2004

FRIADENT GmbH
C/O Ms. Carol Patterson
President
Patterson Consulting Group, Incorporated
21911 Erie Lane
Lake Forest, California 92630

Re: K040946
Trade/Device Name: ANKYLOS® Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: April 7, 2004
Received: April 12, 2004

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K040946

Device Name: ANKYLOS® Dental Implant System

Indications for Use:

An endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healling or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on 4 interforminal placed implants, and not indicated for single, unsplinted implants. Patients must be subject for dental treatment with endosseous implants.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040946

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)